Remarks

A. Pending Claims

Claims 29, 31, 33-34, 38, 42, 45-46, 48-54 and 56 have been rejected. Claims 29 and 56 have been amended. Claim 60 is new. Claims 29, 31, 33-34, 38, 42, 45-46, 48-54, 56, and 60 are pending.

B. The Claims Are Not Anticipated By Heyn Pursuant To 35 U.S.C. § 102(b)

Claims 29, 42, 45-46, 48-51, 54 and 56 were rejected pursuant to 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,201,757 to Heyn et al. ("Heyn"). Applicant respectfully disagrees.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

The Office Action states:

> Heyn discloses a first conduit 44, wherein at least a portion of an endoscope or bronchoscope, having at least a portion that is partially flexible, may be positionable in the first conduit during use, and a second conduit 20, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent 18 between the distal ends of the first and second conduits, and wherein the second conduit is configurable to releasably position the stent in a body lumen or air passage during use (Figure 1, col. 5, lines 15-23).

Applicant respectfully submits that the cited art does not appear to teach or suggest the combination of features in claims 29, 42, 45-46, 48-51, 54 and 56.

Amended claim 29 describes a combination of features including, but not limited to, the feature of: "a first conduit, wherein at least a portion of an endoscope is positionable in the first conduit during use, and wherein the first conduit is sized to allow an endoscope to move through the first conduit." Amended claim 56 describes a combination of features including, but not limited to, the feature of: "a first conduit, wherein at least a portion of a bronchoscope is positionable in the first conduit during use, and wherein the first conduit is sized to allow a bronchoscope to move through the first conduit." Claims 29 and 56 have been amended for clarity.

Applicant discloses:

> Endoscopes are effectively utilized to deploy stents within a body cavity in a minimally invasive manner. In a conventional method, a stent is compressed to fit into the working channel of the endoscope and is delivered to the body cavity to be treated. However, storing a stent within the working channel of an endoscope causes several problems. First, there is a limitation on the size of the stent that can be compressed to fit in the working channel. Because the working channel of the endoscope is often relatively small, a large stent may not fit within the working channel. Thus, this method is not suitable for deploying large stents.
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> Additionally, fitting a stent in the working channel often results in deformation of the stent when it is deployed into the body cavity. Since stents are made of resilient material, compression within the working channel may cause the stent to become deformed and fail to return to its original shape when released from the working channel. The more the stent gets strained, the more the deformation is likely to be.
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> A specific example of the aforementioned problems can be seen when observing commonly used methods for positioning and deploying pulmonary stents. Currently, surgeons insert a bronchoscope into an air passageway of a patient to visually observe where a pulmonary stent needs to be positioned. They typically use a type of guide wire inserted through the bronchoscope to mark the position where they want to place the pulmonary stent. At this point, the bronchoscope is removed and a stent delivery system (typically associated with delivering vascular stents) is used to place the pulmonary stent using the guide wire and fluoroscopy or radioscopy to assist in positioning. This current technique requires several distinct and difficult steps and does not allow the surgeon to visually observe the actual placement of the stent. There is a need for a

stent delivery system which allows for visual observation during placement of the stent and which requires fewer steps. (Specification, page 1, lines 22-40).

Heyn discloses:

> The device includes an elongate and flexible outer catheter 20 constructed of a biocompatible polymer, e.g. polyurethane, with an outside diameter of 0.12 inches or smaller. A central lumen 22 runs the length of catheter 20. A distal portion 24 of catheter 20 provides a sleeve that surrounds a proximal region 26 of stent 18. Sleeve 24 is inclined at its distal end to provide a frusto-conical inside surface 28 that facilitates release and recapture of stent 18.
>
> A distal sleeve 30 is contiguous with sleeve 24 at an annular interface 32. Sleeve 30 is formed at its proximal end with an inclined surface 34 similar to surface 28, and for the same purpose. A passage 36 through the distal sleeve forms a continuation of lumen 22, for a distal region 38 of the stent.
>
> The distal end of sleeve 30 is fixed to a tapered distal tip 40, in an annular recess 42 formed in the tip. Also fixed to the distal tip is an inner catheter 44 with an outside diameter of approximately 0.08 inches or smaller and running substantially the length of device 16. Stent 18 surrounds inner catheter 44, and thus is confined between the inner and outer catheters. A lumen 46 in the inner catheter contains a flexible guide wire 48, and further is suitable for supplying fluids from the proximal end of the device for priming and addition of contrast media. The inner catheter is fixed into a cylindrical recess 50 formed in the distal tip, and the tip has a passage 52 continuing lumen 46. (Heyn, column 5, lines 15-42).

Heyn discloses:

> A lumen 46 in the inner catheter contains a flexible guide wire 48, and further is suitable for supplying fluids from the proximal end of the device for priming and addition of contrast media. The inner catheter is fixed into a cylindrical recess 50 formed in the distal tip, and the tip has a passage 52 continuing lumen 46. (Heyn, column 5, lines 36-42).

In addition, Heyn discloses:

> FIG. 2 shows a stent deployment device 74 similar to device 16 in that it includes an outer catheter 76 and an inner catheter 78 contained in a lumen 80 of the outer catheter. The inner catheter and a distal sleeve 82 are fixed to a tapered distal tip 84. A guide wire 86 is contained within a lumen 88 of the inner catheter and a

> passage 90 through the distal tip. Control means are provided near the proximal end of the device, including a finger grip 92 for moving a sleeve portion 94 of the outer catheter, and an end member 96 and tubular section 98 for axially moving inner catheter 78 and distal sleeve 82. (Heyn, column 6, lines 35-46).

Heyn further discloses:

> A fluid lumen 208 in inner catheter 194 is open to the chamber, for supplying fluid under pressure to the chamber. Catheter 194 includes another lumen 210 to accommodate a guide wire 212. (Heyn, column 9, lines 53-56).

In addition Heyn discloses:

> An inner catheter 232, contained within lumen 226, runs substantially the length of the device, including a substantial distal portion extending beyond the distal end of outer catheter 224. A tapered distal tip 234 is fixed to the distal end of inner catheter 232. A distal sleeve 236, also fixed to the distal tip, surrounds the inner catheter. A lumen 238 through inner catheter 232 contains a guidewire 240, and also is suitable for supplying fluids from a proximal end of the device, for priming and an addition of contrast media. The inner catheter is fixed to a cylindrical recess formed in the distal tip, and the tip has a passage continuing lumen 238. (Heyn, column 10, lines 13-24).

Heyn appears to teach or suggest an apparatus for deploying a radially self-expanding stent including an inside catheter having a lumen to accommodate **a guide wire** used to initially position the catheters. Specifically Heyn teaches an inner conduit (44) with an outside diameter of approximately 0.08 inches or smaller in which a guide wire is positioned. Applicant is not aware of an endoscope which is small enough to be positioned and moved within the inner conduit described by Heyn. Applicant discloses a stent delivery system which does not require the use of a guide wire to position a stent, but is configured to allow the use of an endoscope to assist in positioning the stent in order to overcome problems associate with use of a guide wire. Heyn does not appear to teach or suggest a stent delivery system comprising the combination of features in Applicant's claims, including a first conduit wherein the first conduit is sized to allow an endoscope and/or a bronchoscope to move through the first conduit. Applicant submits Heyn does not appear to teach the combination of features in claims 29 and 56 and the claims

dependent thereon.

Applicant believes many of the dependent claims may be separately patentable. For example, claim 48 describes a combination of features including: "wherein at least a portion of the first conduit is configured to inhibit collapse of the first conduit upon removal of the endoscope during use." Applicant submits that at least the quoted features of claim 48, in combination with the other features of the claim, do not appear to be taught by the cited art. As such, Applicant submits claims 29, 42, 45-46, 48-49, 51, 54 and 56 are patentable over Heyn.

C. <u>The Claims Are Not Obvious Over Heyn In View of Bui Pursuant To 35 U.S.C. § 103(a)</u>

Claim 31 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 6,629,981 to Bui et al. ("Bui"). Applicant respectfully disagrees.

To reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.,* 379 F.2d 1011, 154 USPQ 173, 177-178 (CCPA 1967). To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP § 2143.03.

The Office Action states:

> Heyn discloses the claimed device except for a first lock configurable to inhibit movement of the first conduit relative to the second conduit during use, and a second lock configurable to inhibit the movement of the endoscope relative to the first conduit during use.

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claim 31 is patentable over the cited art at least for the reasons cited in Section B.

The Office Action states:

> Bui teaches a first lock 110 configurable to inhibit movement of the first conduit relative to the second conduit during use, and a second lock configurable to inhibit movement of the endoscope 124 relative to the first conduit during use (Figures 11, 15-17, and col. 9, lines 43-52 and col. 11, lines 8-19). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a first lock and a second lock, as taught by Bui, to Heyn since it was known in the art that undesirable axial movement of coaxial conduits, or sleeves, results in difficult or undesirable deployment or lack of visibility, and therefore inhibiting movement between first and second conduits facilitates deployment of the stent.

Applicant respectfully disagrees. Claim 31 describes a combination of features including, but not limited to, the feature of: "a first lock configurable to inhibit movement of the first conduit relative to the second conduit during use; and a second lock configurable to inhibit movement of the endoscope relative to the first conduit during use."

Bui discloses:

> FIG. 11 illustrates the stent delivery device after the stent 10 has been deployed. As shown, at the proximal end of the main body 102, and provided within slot 122, an endoscope 124 is locked into place against the main body 102. The endoscope 124 preferably includes a first port 126 for receiving a light source and a second port 128 for visualization. The endoscope 124, when inserted into the main body 102, preferably forms a fluid tight seal therewith, on the proximal side of the irrigation port. (Bui, column 9, lines 43-52).

Bui further discloses:

> FIGS. 15-17 illustrate the operation of the device 100 according to one embodiment of the present invention and in accordance with the delivery techniques described with respect to FIGS. 4-8 above. The endoscope 124 described above is first inserted into the proximal end of the delivery device 100. The delivery system is pushed through the urethra until the stent is located in the prostatic urethra 3. Visualization using the endoscope through the lumen of the inner catheter 14 is performed so that correct initial placement may be verified visually. Once it is verified that the distal end of the stent 10 is located at the bladder neck, the locking pin 110 is removed to allow movement of the sheath 16. (Bui, column 11, lines 8-19).

Bui appears to teach or suggest a device wherein a slot 122 in the main body 102 locks an endoscope 124 into place against the main body 102. Bui appears to teach or suggest retaining pin 110, which prevents the sheath 16 from moving while the pin is in place. Bui does not appear to teach or suggest a combination of features including, but not limited to, the feature of: "a second lock configurable to inhibit movement of the endoscope relative to the first conduit during use." Applicant submits Heyn in view of Bui does not appear to teach all of the features in claim 31.

D. The Claims Are Not Obvious Over Heyn In View of Gunderson Pursuant To 35 U.S.C. § 103(a)

Claims 33-34 and 53 were rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 5,776,142 to Gunderson ("Gunderson"). Applicant respectfully disagrees.

The Office Action states:

> Heyn discloses the claimed device except for a lock configurable to inhibit movement of the first conduit relative to the second conduit during use.

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claims 33-34 and 53 are patentable over the cited art at least for the reasons cited in Section B.

The Office Action states:

> Gunderson teaches a lock configurable to inhibit movement of the first conduit to the second conduit during use, wherein the lock comprises a first grip 20 coupled to at least a portion of the first conduit, and a second grip 30 coupled to at least a portion of the second conduit, and one or more pins 28 coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of

> the first and second conduits from moving transversely to each other wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip (Figure 1, col. 5, lines 7-16).

Applicant respectfully disagrees. Claim 33 describes a combination of features including, but not limited to, the feature of: "a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises: a first grip coupled to at least a portion of the first conduit; and a second grip coupled to at least a portion of the second conduit; wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip." Claim 34 describes a combination of features including, but not limited to, the feature of: "further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises: a first grip coupled to at least a portion of the first conduit; a second grip coupled to at least a portion of the second conduit; and one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other; wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip."

Gunderson discloses:

> With the two handles 20 and 30 fixedly attached to the inner and outer sheaths 40 and 50, it will be understood that rotation of the handles 20 and 30 relative to each other will cause corresponding relative rotation between the inner and outer sheaths 40 and 50. The screw portion 26 of handle 20 and corresponding screw receiving portion 32 of handle 30, it will also be understood that relative rotation of the handles 20 and 30 will also cause relative movement along the longitudinal axis of the device between the inner and outer sheaths 40 and 50 as will be discussed in more detail below. (Gunderson, column 5, lines 7-16).

Gunderson further discloses:

> The handle 20 is preferably fixedly attached to the inner sheath 40 such that rotation of the handle 20 about the longitudinal axis of the device results in corresponding rotation of the inner sheath 40. The handle 20 also preferably includes a screw portion 26 including threads 28 as shown in FIG. 1.
> The second handle 30 preferably includes a threaded opening 32 designed to receive the threads 28 of the screw portion 26 of the first handle 20. Handle 30 is fixedly attached to the outer sheath 50 such that rotation of the handle 30 about the longitudinal axis of the device results in corresponding rotation of the outer sheath 50. Handle 30 also preferably includes a release wire actuator 34 attached to the proximal end of a release wire 56 described more completely below. The actuator 34 is preferably mounted for movement along the longitudinal axis of the stent delivery device. (Gunderson, column 4, line 57 through column 5, line 6).

Gunderson appears to teach or suggest a device including threads 28 of the screw portion 26 of the first handle 20. Gunderson appears to teach or suggest a handle 30 fixedly attached to the outer sheath 50 such that rotation of the handle 30 about the longitudinal axis of the device results in corresponding rotation of the outer sheath 50. Gunderson does not appear to teach or suggest a combination of features including, but not limited to, the feature of: "one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other." Applicant submits Gunderson does not appear to teach all of the features in claims 33 and 34.

Claim 53 describes a combination of features including, but not limited to, the feature of: "wherein the first conduit comprises a polymer." The features of claim 53, in combination with the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art.

E. <u>The Claims Are Not Obvious Over Heyn In View Of Mikus Pursuant To 35 U.S.C. § 103(a)</u>

Claim 38 were rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 6,093,194 to Mikus et al. ("Mikus"). Applicant respectfully disagrees.

The Office Action states:

> Heyn discloses the claimed device except for a lock configurable to inhibit movement of the first conduit relative to the second conduit during use.

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claim 38 is patentable over the cited art at least for the reasons cited in Section B.

The Office Action states:

> Mikus teaches a lock configurable to inhibit movement of a first conduit 70 relative to the second conduit 75 during use, wherein the lock comprises a clamp 77, 78 in order to prevent premature proximal displacement during insertion of the conduits into the body lumen (Figure 7, col. 7, lines 54-67 to col. 8, lines 1-8).

Applicant respectfully disagrees. Claim 38 describes a combination of features including, but not limited to, the feature of: "a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises a clamp." The features of claim 38, in combination with the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art. Applicant submits Heyn in view of Mikus does not appear to teach all of the features in claim 38.

F. <u>The Claims Are Not Obvious Over Heyn In View of Quiachon Pursuant To 35 U.S.C. § 103(a)</u>

Claim 52 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 5,938,623 to Quiachon ("Quiachon"). Applicant respectfully disagrees.

The Office Action states:

> Heyn discloses the claimed device except for the first conduit comprising a coiled spring.

Applicant respectfully disagrees that Heyn discloses the claimed device. Applicant respectfully submits that claim 52 is patentable over the cited art at least for the reasons cited in Section B.

The Office Action states:

> Quiachon teaches a first conduit 42 comprising a coiled spring 61 (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a coiled spring, as taught by Quiachon, to Heyn since it was known in the art that coiled springs used with conduits, sleeves, sheaths or catheters act as dampeners or absorb vibration along the length of a catheter.

Applicant respectfully disagrees. Claim 52 describes a combination of features including, but not limited to, the feature of: "wherein the first conduit comprises a coiled spring configured to inhibit collapse of the first conduit." The features of claim 52, in combination with the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art. Applicant submits Heyn in view of Quiachon does not appear to teach all of the features in claim 52.

G. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

Applicant respectfully requests a two month extension of time. If any further extension of time is required, Applicant hereby requests the appropriate extension of time. Applicant has included a Fee Authorization Form for fees related to Two Month Extension of Time Fee. If any further fees are required, or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5660-01207/EBM.

Respectfully submitted,

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